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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 2003N-0075]

**Agency Information Collection Activities; Submission for OMB Review;  
Comment Request; Administrative Detention and Banned Medical Devices**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Administrative Detention and Banned Medical Devices (OMB Control Number 0910-0114)—Extension**

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 334(g)), to detain during establishment inspections devices that are believed to be adulterated or misbranded. FDA issued a final rule that published in the **Federal Register** of March 9, 1979 (44 FR 13234 at 13239), on administrative detention procedures, which includes, among other things, certain reporting requirements under § 800.55(g) and (k) (21 CFR 800.55(g) and (k)) and recordkeeping requirements. Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, as well as records of distribution of the detained devices. These recordkeeping requirements for administrative detentions allow FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. The final rule for banned devices that published in the **Federal Register** of May 18, 1979 (44 FR 29214 at 29221), contained certain reporting requirements under §§ 895.21(d) and 895.22 (21 CFR 895.21(d) and 895.22). Section 895.21(d) states that if the Commissioner of Food and Drugs (the Commissioner) decides to initiate a proceeding to make

a device a banned device, a notice of proposed rulemaking will be published in the **Federal Register** and this document will contain the finding that the substantial risk of illness or injury exists. The document will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling or change of labeling, or change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

Respondents to this collection of information are those manufacturers, distributors, or importers whose products FDA seeks to detain or ban. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary.

In the **Federal Register** of March 17, 2003 (68 FR 12706), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Total Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22	26	1	26	16	416
Total					441

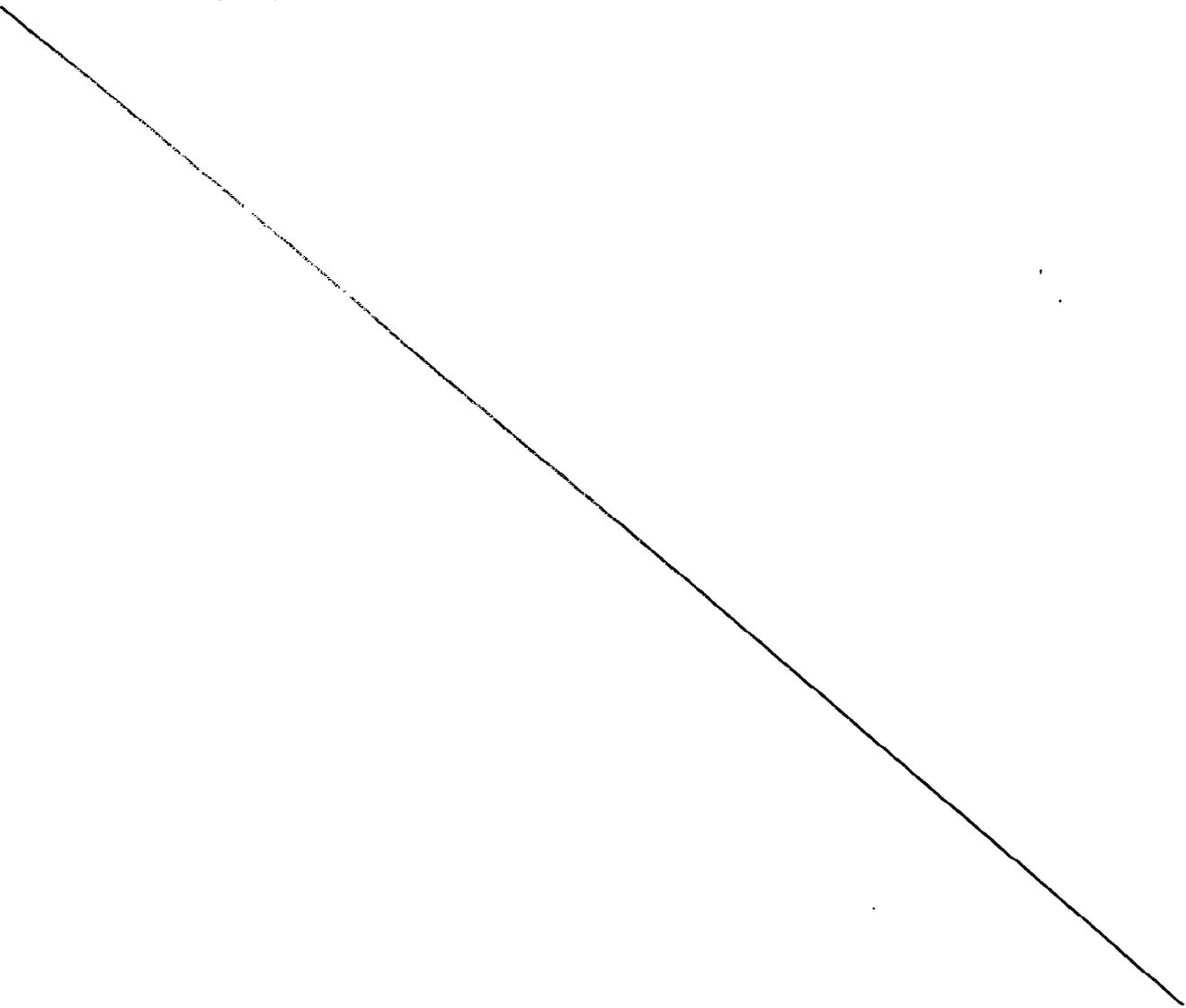
<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
800.55(k)	1	1	1	20	20

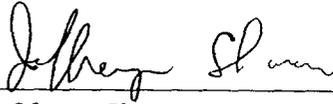
<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Over the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. Historically, the Center for Devices and Radiological Health has had very few or no annual responses for this information collection and normally reports one response per year.



FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the three firms whose devices had been detained.

Dated: 6-16-03  
June 16, 2003.



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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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